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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,547	01/16/2004	Zongcen Charles Xie	033819-071	7118

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EXAMINER	
LEVKOVICH, NATALIA A	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,547	XIE ET AL.	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 20-25, drawn to a glycated hemoglobin detection system, classified in class 422, subclass 61.

II. Claims 7-11, drawn to an analytical composition, classified in class 422, subclass 518.

III. Claims 12-15, drawn to a method of making an analytical kit, classified in class 422, subclass 61.

IV. Claims 16-19, drawn to a method of preparing a sample, classified in class 436, subclass 533.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions II and IV have separate utility such as a composition and method of preparing the composition (correspondingly) for assays involving immune complexes formed in liquid phase. See MPEP § 806.05(d).

3. Inventions III and I, IV and II, are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed

can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the kit and the composition can be used for determination of various constituents of bodily liquids.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Mr. David Heckadon on 05/06/2005 a provisional election was made with the preservation of traverse to prosecute the invention of Group I, claims 1-6 and 20-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Interpretation

6. Claim 1 does not positively recite dry immunoassay reagent system as a part of the claimed apparatus. Applicant is advised to positively claim the reagent system which would allow dependant claims 5-6 and 24-25 (reciting the reagent system) to be considered on the merits .

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d

576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 and 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai (USP 5,882,935).

Hirai teaches a system for quantitatively analyzing glycated hemoglobin, The system "comprises a substrate layer ['device' – Examiner] for receiving a reaction mixture after the completion of an immunological reaction between the glycated hemoglobin in the sample and an enzyme-labelled antibody against the glycated hemoglobin'(Abstract) and a blood dilution solution containing surfactants : "the sample to be analyzed is needed to be subjected to the complete hemolysis so as to fully solubilize the hemoglobin into the solution. A ...hemolysis agent or surfactant (for example, Triton X-100) may be used for this purpose"(Col.6, lines 30-35), as well as other surfactants, added to "improve ...reactivity and storage stability"(Col. 11, line 20). Various types of surfactants can used be for hemolysis: nonionic, ionic, ampholytic ['zwitterionic' – Examiner] (Col. 6, lines 45-50).

With respect to claims 6 and 25, as the dry reagents are not recited as part of the invention, the elements recited therein are accorded no patentable weight.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai (USP 5,882,935) in view of Spring (USP 5,643,721).

If however, Applicant's claims are amended to recite the dry reagent as part of the invention, those limitations are seen as obvious.

Hirai does not teach dry reagent system to be latex particles. Spring discloses an immobilization medium comprising "comprising (a) a bioreagent immobilized to a solid phase and (b) a binding reagent comprising a latex resin, wherein the immobilized bioreagent is evenly

dispersed"(Col.5, line 20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed latex particles in the reagent system in the apparatus of McCormick, in order to evenly disperse immobilized bioreagent.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jill Warden
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